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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/081,081 | 02/20/2002 | Rolando Wyss | 205,530 | 2347 |

7590 05/04/2004

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| EXAMINER | |
|---|---|
| NAVARRO, ALBERT MARK | |
| **ART UNIT** | **PAPER NUMBER** |
| 1645 | |

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/081,081 | WYSS ET AL. | |
| | Examiner | Art Unit | |
| | Mark Navarro | 1645 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *28 January 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *27-51* is/are pending in the application.

4a) Of the above claim(s) *43-46,50 and 51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-42, 47-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

Applicants amendment filed January 28, 2004 has been received and entered. Claims 1-26 have been canceled and new claims 27-51 have been added. Accordingly, claims 27-51 are pending in the instant application.

### *Election/Restrictions*

Newly submitted claims 43-46, and 50-51 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Claims 43-46 and 50-51 are drawn to methods of using the composition which has already been examined. As set forth in MPEP 800, restriction between a product and method of using or method of making is proper if the composition can be used in a materially different process. In the instant application the composition can be used in a method of treatment as claimed, or alternatively may be incorporated into an in vitro assay to detect the antigen.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 43-46 and 50-51 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

All grounds of rejection in the previous Office Action are withdrawn in view of the cancellation of claims 1-26.

The following new grounds of rejection are applied:

### *Claim Rejections - 35 USC § 112*

1. Claim 29 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is vague and indefinite in the recitation of "low molecular weight and a high degree of deacetylation."

Applicants are asserting that the definition of chitosan with high or low degree of deacetylation refers to a 100% degree of acetylation of chitin, and that those of skill in the art are also aware of the definition of high and low molecular weight chitosan, for example WO 98/30207. Applicants arguments have been fully considered but are not found to be fully persuasive.

First, although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Consequently, the metes and bounds of the terms "high or low degree" and "high or low" molecular weight are relative terms that can differ from one reference to another. Therefore, one of skill in the art would be unable to determine the metes and bounds of the claimed invention.

For reasons of record, as well as the reason set forth above, this rejection is maintained.

### *Claim Rejections - 35 USC § 102*

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 27-30, 32-34, and 48-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Watts et al.

Applicants are asserting that Watts discloses of a three component mixture comprising chitosan, gelatin and the active principle, and that claims 27-45 recite consisting of polysaccharides and immunoglobulins.

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, Applicants claims do not recite "consisting of" as Applicants assert, rather the transitional phrase "consisting essentially of" is employed.

Finally, as set forth in MPEP 211.03 "For the purposes of searching for and applying prior art under 35 USC 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are "consisting essentially of" will be construed as equivalent to "comprising" See e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355 ("PPG could have defined the scope of the phrase consisting essentially of" for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention."). Given that Applicants specification does not set forth of the basic and novel characteristics the term "consisting essentially of" has been deemed to be equivalent to comprising.

For reasons of record as well as the reasons set forth above, this rejection is maintained.

***Claim Rejections - 35 USC § 103***

3. Claims 27-42, and 47-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gombotz et al and Watts et al in view of Anderson et al, Griffin et al, Garner et al and Costa et al.

The claims are drawn to isolated compositions consisting essentially of immunoglobulins, as the active ingredient, and a polysaccharide selected from the group consisting of chitosanes and alginates, wherein the molecules of polysaccharide are neither chemically cross-linked to the immunoglobulins, nor to each other.

Applicants are asserting that each of the Gombotz et al and Watts et al references fails to disclose of a composition consisting of antibodies and polysaccharide as instantly claimed. Applicants further assert that Watts uses a further component (gelatin) to achieve properties similar to those obtained with reticulation.

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, as noted above, Applicants claims are not drawn to "consisting of" as argued, rather the claims recite "consisting essentially of." These arguments have been fully addressed above.

Finally, Applicants assert that Watts uses a further component (gelatin) to achieve properties similar to those obtained with reticulation. However, Applicants

claims recite "consisting essentially of" as such, additional chemical such as gelatin are not excluded in view of PPG, 156 F.3d at 1355, 48 USPQ2d at 1355.

For reasons of record, as well as the reasons set forth above this rejection is maintained.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark Navarro
Primary Examiner
May 3, 2004